REMARKS:

The Applicants filed a Preliminary Amendment on September 26, 2002. Because the Preliminary Amendment was filed after the mailing date of the Office Action,

Applicants have reintroduced the amendments made in the Preliminary Amendment.

The Examiner has withdrawn claims 10-39 and 41-46. Claims 2, 3, and 40 have been cancelled and claims 1 and 4-9 have been amended without prejudice or disclaimer. New claims 47-71 have been added. A marked-up version of the claims is included in the attached Appendix. As set forth below, these amendments and new claims are fully supported by the specification and originally filed claims. With the entry of this amendment, claims 1, 4-9, and 47-71 are under consideration.

Support for the claim amendments can be found, for example, in the Table describing "Amended Claims" given below.

Amended Claims

Claim No. and Amendment	Support for Amendments
1 " large scale"	Page 1, lines 16-17; page 11, lines 26-28.
" in high to quantitative yield and without the need for chromatographic purification"	Page 2, lines 20-21; page 10, lines 18-20; and page 11, lines 26-28.
" wherein the hydrogenation step is performed with hydrogen in the presence of at least one reduction catalyst and at least one solvent."	Original claim 2.
4 " alumina powder, and"	Page 9, lines 28-33
5 " about 10% palladium"	Page 10, lines 20-22.
8 " <u>absolute</u> methanol, <u>absolute</u> ethanol, and <u>ethyl</u> acetate."	Page 10, lines 13-14.

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In addition to the claim amendments described in the table above, claims 4-9 have also been amended to change claim dependencies and to present claims in a proper Markush format.

New claims 47-71 have been added. New claims 47-56 ultimately depend from claim 1. Support for these new claims can be found, for example, in the originally filed claims and throughout the specification as indicated below in the Table describing "New Claims."

New claim 57 is similar to originally-filed claim 40, but has incorporated the language of claim 1 and is presented as an independent claim. New claims 58-71 depend ultimately from new claim 57. Support for these new claims 57-71 can be found, for example, in the originally filed claims and throughout the specification as described in the Table "New Claims" below.

New Claims

Claim No.	Support for New Claims
47	Page 9, lines 28-33.
48	Original claim 9.
49	Page 10, lines 13-14.
50	Originally filed claim 7.
51	Page 10, line 31 to page 11, line 4.
52	Example 13; page 18, line 11 to page 19, line 3.
53	Page 20, lines 7-10
54	Page 18, lines 27-29
55	Page 10, lines 1-3.
56	Page 11, lines 28-30.
57	Original claims 1 and 40

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Original claim 4.
Original claim 6.
Original claim 5.
Page 9, lines 28-33.
Original claim 7.
Original claim 8 and page 10, lines 13-14.
Original claim 9.
Original claim 9.
Page 10, lines 13-14.
Original claim 7.
Page 10, line 31 to page 11, line 4.
Example 13; page 18, line 11 to page 19, line 3.
Page 20, lines 7-10
Page 18, lines 27-29

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 40 as allegedly indefinite under 35 U.S.C. §112, second paragraph. Specifically, the Examiner stated the language "any preceding claim" renders the claim indefinite. Office Action, page 4. Without acquiescing to the rejection, claim 40 has been cancelled, and the rejection is moot.

Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §112, second paragraph rejection.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 1-9 and 40 under 35 U.S.C. §102(b) as allegedly anticipated by Szabo et al. (Szabo) and Inoue.

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To anticipate a claim, the reference must teach every element of the claim.

Manual of Patent Examining Procedure (MPEP), §2131. Without acquiescing to the rejection, claim 1 has been amended to recite "[a] method for the large scale preparation of a compound of formula II ... in high quantitative yield and without the need for chromatographic purification" emphasis added.

Neither Szabo nor Inouye teach a method of large scale preparation. In addition, neither Szabo nor Inouye teach a method of preparation of compound of formula II in high quantitative yield or without the need for chromatographic purification. Neither Szabo nor Inouye anticipate claim 1.

Claim 40 has been cancelled. Claims 4-9 ultimately depend from claim 1. Thus, claims 4-9 are also not anticipated by either Szabo or Inouye. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claim Objection

The Examiner objected to claim 40 as allegedly containing non-elected subject matter. Office Action, page 4. Without acquiescing to the objection, claim 40 has been cancelled, and the rejection is moot.

Conclusion

Applicants respectfully request the reconsideration and withdrawal of all claim rejections. Furthermore, Applicants respectfully request the timely allowance of all pending claims.

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If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: January 22, 2003

Robert W. Ma

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APPENDIX

1. (Amended) A method for the large scale preparation of a compound of formula II

$$R_1$$
 R_6
 R_5
 R_8
 R_4
 R_8
 R_2
(III)

wherein

R₁, R₂, R₃, R₄, R₅, R₆, R₇ and R₈ are independently hydrogen, hydroxy, OR₉, OC(O)R₉, OS(O)R₉, alkyl, haloalkyl, aryl, arylalkyl, thio, alkylthio, amino, alkylamino, dialkylamino, nitro, or halo[,]; and

R₉ is alkyl, haloalkyl, aryl, arylalkyl or alkylaryl[,];

in high to quantitative yield and without the need for chromatographic purification; comprising the step of hydrogenating a compound of formula I

$$\begin{array}{c|c}
R_1 & C & R_8 \\
R_6 & R_5 & C & R_3
\end{array}$$

$$\begin{array}{c|c}
R_4 & (I) \\
R_8 & R_2 & R_2
\end{array}$$

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1300 I Street, NW Washington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com wherein

R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈ and R₉ are as defined above;

to prepare a compound of formula II; and

wherein the hydrogenation step is performed with hydrogen in the presence of at least

one reduction catalyst and at least one solvent.

- 4. (Amended) A method of claim [3] 1, wherein the at least one reduction catalyst is selected from palladium on activated carbon, palladium on barium sulfate, alumina powder, and [or] platinum (IV) oxide.
- 5. (Amended) A method of claim [3] 4, wherein the at least one reduction catalyst is about 10% palladium on activated carbon [(1% Pd to 10% Pd)].
- 6. (Amended) A method of claim [5] 4, wherein the at least one reduction catalyst is about 5% palladium on activated carbon.
- 7. (Amended) A method of claim [2] 1, wherein the at least one solvent is selected from a C₁-C₈ alcohol, an alkyl acetate, and [or] a C₁-C₃ carboxylic acid.
- 8. (Amended) A method of claim [2] 7, wherein the <u>at least one</u> solvent is <u>absolute</u> methanol, <u>absolute</u> ethanol, <u>or absolute ethyl</u> [or C₁-C₆ alkyl] acetate.
- (Amended) A method of claim 8, wherein the <u>at least one</u> solvent is absolute methanol [or absolute ethanol].

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